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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,861	07/03/2002	Carlos Cordon-Cardo	55293-B-PCT-US/JPW/FHB	6709
57539	7590	06/30/2006	EXAMINER	
COOPER & DUNHAM LLP			UNGAR, SUSAN NMN	
1185 AVENUE OF THE AMERICAS			ART UNIT	PAPER NUMBER
NEW YORK, NY 10036			1642	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.		Applicant(s)	
	10/009,861		CORDON-CARDO ET AL.	
	Examiner		Art Unit	
	Susan Ungar		1842	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☒ This action is FINAL                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 19 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 19 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

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1. The Amendment filed April 27, 2006 in response to the Office Action of December 21, 2005 is acknowledged and has been entered. Previously pending claim 30 has been cancelled, claim 19 has been amended. Claims 19 and 28 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

*New Grounds of Rejection*  
*Claim Rejections - 35 USC 112*

3. Claims 19 and 28 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of prostate cancer cells which overexpress HER-2/neu protein claimed in Claim 19 and 28 has no clear support in the specification and the claims as originally filed. Applicant points to support for the newly added limitations of claim 19 in the originally filed claim 30 as well as in the specification at page 103, lines 31-33 and states that the remaining changes to claim 19 introduce minor format changes. The cited support has been considered but has not been found persuasive because a review of claim 30 reveals that it is drawn to androgen independent prostate cancer but is not drawn to androgen-independent prostate cancer cells that overexpress HER-2/neu. Further, a review of page 103, lines 31-33 reveals support for Paclitaxel and Herceptin cotreatment leading to greater growth inhibition than was seen for the agents individually. Thus, none of the support cited for this amendment is drawn to the amendment. Further, it is noted that the newly added limitation is not a minor format change but rather changes the scope of the claimed invention. The subject matter claimed in claims 19 and 28 broadens the scope of the invention as originally disclosed in the specification.

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4. Claims 19 and 28 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a method comprises administering a monoclonal antibody which selectively binds to the extracellular domain of HER-2/neu protein claimed in Claim 19 and 28 has no clear support in the specification and the claims as originally filed. Applicant points to support for the newly added limitations of claim 19 in the originally filed claim 30 as well as in the specification at page 103, lines 31-33 and states that the remaining changes to claim 19 introduce minor format changes. The cited support has been considered but has not been found persuasive because a review of claim 30 reveals that it is drawn to androgen independent prostate cancer but is not drawn to selective binding to HER-2/neu expressed on androgen-independent prostate cancer cells. Further, a review of page 103, lines 31-33 reveals support for Paclitaxel and Herceptin cotreatment leading to greater growth inhibition than was seen for the agents individually. Thus, none of the support cited for this amendment is drawn to the amendment. Further, it is noted that the newly added limitation is not a minor format change but rather changes the scope of the claimed invention. The subject matter claimed in claims 19 and 28 broadens the scope of the invention as originally disclosed in the specification.

5. Claims 19 and 28 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of treatment wherein treatment with the monoclonal antibody and the chemotherapeutic agent inhibits prostate cancer cell growth more than treatment with either the monoclonal antibody alone or the chemotherapeutic agent alone claimed in Claim 19 and 28, in the absence of the recitation that the

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chemotherapeutic agent is paclitaxel, has no clear support in the specification and the claims as originally filed. Applicant points to support for the newly added limitations of claim 19 in the originally filed claim 30 as well as in the specification at page 103, lines 31-33 and states that the remaining changes to claim 19 introduce minor format changes. The cited support has been considered but has not been found persuasive because a review of claim 30 reveals that it is drawn to androgen independent prostate cancer but is not drawn to additive or synergistic properties of the claimed method. Further, a review of page 103, lines 31-33 reveals support for Paclitaxel and Herceptin cotreatment leading to greater growth inhibition than was seen for the agents individually. This statement does not support the newly added broad limitation drawn to the combination of any chemotherapeutic drug with antibody to extracellular domain of HER-2/neu. Thus, none of the support cited for this amendment is drawn to the amendment. Further, it is noted that the newly added limitation is not a minor format change but rather changes the scope of the claimed invention. The subject matter claimed in claims 19 and 28 broadens the scope of the invention as originally disclosed in the specification.

6. No claims allowed.

7. All other objections and rejections set forth in the previous office action are hereby withdrawn.

8. Applicant's amendments necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

**A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN**

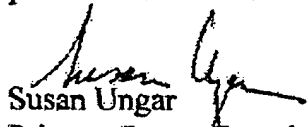
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TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

  
Susan Ungar  
Primary Patent Examiner  
June 27, 2006